

REMARKS

Formalities

Claims 1-96 have been canceled. Claims 97-127 are added. The newly added claims do not add or constitute new matter, and are supported by the application as originally filed. Support may be found throughout the specification and in the originally filed claims.

The foregoing amendments are made solely to expedite prosecution of the instant application, and are not intended to limit the scope of the invention. Furthermore, the amendments are made without prejudice to the pending or now canceled claims or to any subject matter pursued in a related application. Applicants reserve the right to prosecute any canceled subject matter at a later time or in a later filed divisional, continuation, or continuation-in-part application.

Applicants request entry and consideration of the foregoing amendments. Upon entry of the amendment, claims 97-127 are pending in the instant application.

Rejections under 35 U.S.C. § 112, first paragraph

Written Description

The Examiner has rejected claims 59-61 and 90-94 under 35 U.S.C. § 112, first paragraph, for allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants respectfully traverse this rejection.

In particular, the Examiner asserts that the methods recited in claims 59-61 and 90-94, which generally relate to methods of identifying agents, wherein the methods involve expression or function of the ROR γ gene in a ROR γ gene knockout mouse, are not described in the specification. More particularly, the Examiner states that “it is not known how to determine the expression or function of a gene that has already been knockout out” (Office Action dated August 12, 2003, page 3).

Applicants respectfully disagree. However, claims 59-61 and 90-94 have been canceled in the instant amendment, rendering this rejection moot. Applicants therefore, respectfully request withdrawal of the rejection under 35 U.S.C. § 112, first paragraph. New claims 97-127 no longer recite a step requiring determination of the expression or function of the ROR γ gene in a mouse in which this gene has been knocked out or disrupted. Applicants submit that new claims 97-127 overcome the instant rejection and meet the requirements and are patentable under 35 U.S.C. § 112, first paragraph.

Enablement

The Examiner has rejected claims 50-58, 62-89, 95 and 96 under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claim. Applicants respectfully traverse this rejection.

Specifically, the Examiner asserts that while the specification is enabling for a transgenic mouse whose genome comprises a homozygous disruption of the ROR γ gene, the nucleotide wherein no ROR γ is produced, and said mouse exhibits phenotypic features such as increased spleen weight, thymic cortical expansion, medullary reduction, lack of lymph nodes, lymphoid infiltrates, or lymphoma, as compared to a wild-type mouse, and a method of producing said mouse by homologous recombination in mouse ES cells, does not reasonably provide enablement for transgenic and/or knockout mice without any phenotype, for a transgenic mouse or cell comprising any kind of disruption in the ROR γ gene or a method of producing said mouse by homologous recombination in any type of cell.

Applicants submit that new claims 97-127 are fully enabled by the instant specification and overcome the Examiner's enablement rejection under 35 U.S.C. § 112, first paragraph. More particularly, these claims recite a transgenic mouse whose genome comprises a disruption in the ROR γ gene, wherein where the disruption is **homozygous**, the mouse **lacks production of functional ROR γ protein** and exhibits the phenotypes described in and enabled by the specification. Further, these claims recite a method of producing the transgenic mouse using homologous recombination **in embryonic stem cells**. Applicants believe that the cancellation of claims and submission of new claims overcomes this rejection.

With respect to the Examiner's assertions that the specification does not enable the phenotypes of increased liver weight and liver to body weight ratio, and increased kidney weight and kidney to body weight ratio for male mice, or increased thymus weight and thymus to body weight ratio for either gender of transgenic mouse (Office Action dated August 12, 2003, page 6), the Applicants respectfully disagree. Applicants point the Examiner to page 53 of the specification, which describes the increased weights, size and discoloration of the liver (lines 2-5), kidney (lines 7-9) and thymus (lines 10-12) in the transgenic mice of the present invention. The Examiner in her conclusions has relied on Table 1, whereas Applicants have specifically disclosed the differences in these organ weight observables in terms of the fold-increase in

weights (*e.g.* “Thymus weights and thymus:body weight ratios were approximately 10 to 30 times greater than in wild-type control mice” – see Page 53, lines 10-11 of the specification). Further, the Examiner also appears to require a standard of statistical significance (for a phenotypic difference) for patentability of the transgenic mouse. However, Applicants are not aware of any such standard. If such a standard does exist, Applicants request the Examiner refer them to information and rules regarding such a standard.

In view of the cancellation of claims 50-58, 62-89, 95 and 96, the submission of new claims 97-127, and the arguments set forth above, the Examiner’s rejection of these claims under 35 U.S.C. § 112, first paragraph, for enablement is no longer relevant. Applicant, therefore, respectfully requests withdrawal of the rejection under 35 U.S.C. § 112, first paragraph. Applicants submit that new claims 97-127 fully meet the requirements and are patentable under 35 U.S.C. § 112, first paragraph.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 54-56, 57, 59-87 and 90-96 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claims 54-56, 57, 59-87 and 90-96 are canceled by this amendment. Applicants disagree with the Examiner’s assertions and respectfully traverse the rejection under 35 U.S.C. § 112, second paragraph. However, in view of the cancellation of these claims, the Examiner’s rejection is no longer relevant.

The Applicants submit that new claims 97-127 are definite and particularly point out and distinctly claim the subject matter regarded as the invention in accordance with 35 U.S.C. § 112, second paragraph. Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

Rejections under 35 U.S.C. § 103(a)

Claims 50-58 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Mansour *et al.* (*Nature* Vol. 336, No. 24, 348-352 (1988)) in view of Medvedev *et al.* (*Genomics* Vol. 46, 93-102 (1997)). Claims 50-58 have been canceled. Applicants disagree with the Examiner’s assertions and respectfully traverse this rejection. However, as a result of the cancellation of claims 50-58, the Examiner’s rejection under 35 U.S.C. § 103(a) is no longer relevant.

New claims 97-127 relate to a transgenic mouse whose genome comprises a disruption in the endogenous ROR γ gene, wherein the mouse exhibits ... phenotype, to cells obtained from said mouse, a method of making said mouse, targeting construct used to make said mouse, and methods of using the mouse to screen for therapeutic agents. Applicants submit that new claims 97-127 are not obvious in view of the teachings of the cited references.

Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 103(a) in light of the amendment to the claims.

It is believed that the claims are currently in condition for allowance, which action is earnestly solicited. The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, or credit any overpayment, to Deposit Account No. 50-1271 under Order No. R-409.

Respectfully submitted,

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Enclosures

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I hereby certify that this correspondence and its listed enclosures are being deposited with the United States Postal Service as First Class Mail, postage paid, in an envelope addressed to: U.S. Patent and Trademark Office, Mail Stop Sequence, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22213-1450, on **January 12, 2004**.

Signed: Don Mixon
Name: Don Mixon

Date: 01/12/04